

**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
FOR THE PREMARKET NOTIFICATION FOR THE
Exactech Sterile Modular Drill Bit**

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Exactech®, Inc.

Establishment Registration Number 1038671

APR 23 1996

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Director Regulatory Affairs

Exactech Sterile Modular Drill Bit

The Exactech Sterile Modular Drill Bit is made of similar materials and is of a similar design to devices that were on the market before May 28, 1976. Additionally, the Sterile Drill Bit is of a similar design to other devices on the market that have been determined to be equivalent to devices on the market prior to May 28, 1976. These predicates include, but are not limited to:

- DePuy Drill Bit

Similarities/Dissimilarities:

The DePuy drill system is similar to the Exactech system in that the cross pin in the bit and the bayonet locking mechanism operate in a like fashion. The flex shafts are both multiple wrapped springs. They differ in the diameters and lengths of the bits that are offered in the system. The DePuy flex shaft is slightly longer and the Exactech flex shaft is slightly stiffer. The DePuy shaft has a Hudson locking end and the Exactech flex shaft has a Trinkle locking end. The 45° fixed angle drivers are similar in all fashions.

Exactech, Inc. has supplied advertisements, brochures and/or catalog information from these companies to the FDA as evidence of equivalency. This literature is in the public domain. In addition, Exactech has provided the FDA design drawings, material specifications and photos of the Sterile Modular Drill Bit.

1. Classification

This device is appropriately placed in FDA classification:

Drill: Bit, Drill. Number 87HTW, Class I device, under 21 CFR 888.4540.

2. Common Name: Drill Bit

3. Trade Name: Exactech Sterile Modular Drill Bit

4. Device Description

The Exactech Sterile Drill Bit is intended for use in orthopedic procedures for drilling bone. The drill bit is designed with a 120° point angle for smooth, effective, bone cutting. The 30° helix angle maintains strength, but provides an efficient channel by which cut bone may escape. The outer diameter (OD) tolerance and associated drill bit guide geometry minimize drill bit damage.

The five (5) modular bits are designed in long and short versions. They have a high tolerance press fit cross pin that provides easy assembly and disassembly with positive bayonet style locking capability in both the flexible and fixed angle drill bit drivers.

All bits are constructed of 455 stainless steel for strength, hardness and resistance to wear.

5. Material Specifications

The Sterile Drill Bits are constructed of Custom 455® stainless steel.

6. Mechanical Properties

Typical mechanical properties can be found in the Carpenter Technology manual: Custom 455® Stainless section.

7. Sterilization

The Exactech Sterile Drill Bits will be supplied sterile. They will be sterilized in their final, sealed packages by gamma irradiation at a contract sterilization facility. The sterilization protocol will be based on the Guidelines for Radiation Sterilization of Medical Devices, issued by the Association for Advancement of Medical Instrumentation Process Control.

Indications:

The Sterile Modular Drill Bit is indicated for use in general orthopedic procedures to predrill bone in preparation for bone screw placement

Manufacturing/Packaging/Sterilization Sites:Manufacturing/Packaging:

Exactech® Inc.
4613 NW 6th Street
Gainesville, FL 32609
Phone: 352/ 377-1140
Fax: 352/ 378-2617

FDA Establishment No: 1038671

Contract Sterilization Sites:

Sterigenics International
305 Enterprise Drive
Westerville, Ohio 43081-8827
Phone: (614) 888-4077
Fax: (614) 888-4223

FDA Establishment No: 1526534

Sterigenics International
18011 Withers Cove Park Drive
Charlotte, North Carolina 28273
Phone: (704) 588-6877
Fax: (704) 588-8355

FDA Establishment No: 1058584

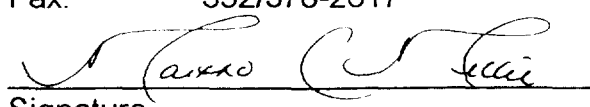
Applicant or Sponsor:

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